510(k) Summary
Mercury™ Spinal System

JAN 22 2009

510(k) Number K082353

Manufacturer Identification

Submitted by:
Spinal Elements, Inc
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760-607-0121

Contact Information:
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Date Prepared: August 13, 2008

Device Identification

Proprietary Name	Mercury™ Spinal System
Device Classification	Spinal Interlaminal Fixation and Spinal Intervertebral Fixation Orthosis and/or Pedicle Screw System (per 21 CFR Section 888 3050, 888 3060 and/or 888 3070)
Regulatory Class	Class III
Device Product Code	MNI, MNH, KWP, KWQ, NKB

Device Description

Spinal Elements' Mercury Spinal System is comprised of a variety of screws, rods, and staples that are used for attachment to the non-cervical spine (T1-S1) A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient Rods span the distance between screws and achieve fixation by the mechanical joining of the rods with the screws Staples (when used) are placed under the head of the polyaxial or monoaxial screws to help distribute loads placed against the bone

Screws, rods, and staples are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3

The devices of this submission are new screw designs and sizes that are being added to the existing system

K082353

Intended Use of the Device

The Mercury Spinal System is intended for fusion procedures of the thoracic, lumbar, and sacral spine (T1-S1) of skeletally mature patients This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i e , fracture or dislocation), spinal stenosis, curvatures (i e , scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion

Substantial Equivalence

The Mercury Spinal System was shown to be substantially equivalent through comparison to the following predicate spinal systems Mercury Spinal System by Spinal Elements (K071914), CD Horizon® Spinal System by Medttronic Sofamor Danek (K063670), Moss Miami Spinal System by DePuy Acromed (K030383), XIA®/XIA® 4 5 Spinal Systems by Stryker Spine (K061854), Omega21™ Degenerative Spine System by EBI Spine (K031354), and USS by Synthes (K000450)

Performance Data

Mechanical testing indicates that Mercury Spinal System devices are capable of performing in accordance with their intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2009

Spinal Elements, Inc
c/o Ms Kerri DiMartino
Regulatory Affairs Specialist
2744 Loker Ave W , Suite 100
Carlsbad, CA 92010

Re K082353
Trade Name Mercury™ Spinal System
Regulation Number 21 CFR 888 3050, 888 3060, and 888 3070
Regulation Name spinal interlaminal fixation, spinal intervertebral fixation orthosis and/or pedicle screw system
Regulatory Class III
Product Code NKB, MNI, MNH, KWP, and KWQ
Dated January 16, 2009
Received January 21, 2009

Dear Ms DiMartino

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050 This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Mark N Melkerson

Mark N Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082353

Device Name: Mercury™ Spinal System

Indications for Use:
The Mercury Spinal System is intended for fusion procedures of the thoracic, lumbar, and sacral spine (T1-S1) of skeletally mature patients. This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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